

World Journal of *Gastrointestinal Endoscopy*

World J Gastrointest Endosc 2021 August 16; 13(8): 238-355



REVIEW

- 238 Six intragastric balloons: Which to choose?
Stavrou G, Shrewsbury A, Kotzampassi K
- 260 Endoscopic retrograde cholangiopancreatography: Current practice and future research
Sanders DJ, Bomman S, Krishnamoorthi R, Kozarek RA
- 275 Indications and outcomes of endoscopic resection for non-pedunculated colorectal lesions: A narrative review
Shahini E, Libânio D, Lo Secco G, Pisani A, Arezzo A

MINIREVIEWS

- 296 Endo-hepatology: An emerging field
Hogan DE, Ma M, Kadosh D, Menon A, Chin K, Swaminath A
- 302 Endoscopic ultrasound-guided biliary drainage: Are we there yet?
Pawa R, Pleasant T, Tom C, Pawa S

ORIGINAL ARTICLE**Retrospective Study**

- 319 Thoracoscopic esophagectomy is related to better outcomes in early adenocarcinoma of esophagogastric junction tumors
Takeda FR, Obregon CA, Navarro YP, Moura DTH, Ribeiro Jr U, Aissar Sallum RA, Cecconello I

Prospective Study

- 329 Prospective evaluation of the hemorrhoid energy treatment for the management of bleeding internal hemorrhoids
Kothari TH, Bittner K, Kothari S, Kaul V

SYSTEMATIC REVIEWS

- 336 Effect of pancreatic endotherapy on quality of life in chronic pancreatitis patients: A systematic review
Han SY, Papachristou GI, Shah RJ, Conwell DL

META-ANALYSIS

- 345 Efficacy and safety of endoscopic transpapillary gallbladder drainage in acute cholecystitis: An updated meta-analysis
Jandura DM, Puli SR

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The primary aim of *World Journal of Gastrointestinal Endoscopy* (WJGE, *World J Gastrointest Endosc*) is to provide scholars and readers from various fields of gastrointestinal endoscopy with a platform to publish high-quality basic and clinical research articles and communicate their research findings online.

WJGE mainly publishes articles reporting research results and findings obtained in the field of gastrointestinal endoscopy and covering a wide range of topics including capsule endoscopy, colonoscopy, double-balloon enteroscopy, duodenoscopy, endoscopic retrograde cholangiopancreatography, endosonography, esophagoscopy, gastrointestinal endoscopy, gastroscopy, laparoscopy, natural orifice endoscopic surgery, proctoscopy, and sigmoidoscopy.

INDEXING/ABSTRACTING

The WJGE is now abstracted and indexed in Emerging Sources Citation Index (Web of Science), PubMed, PubMed Central, China National Knowledge Infrastructure (CNKI), and Superstar Journals Database. The 2021 edition of Journal Citation Reports® cites the 2020 Journal Citation Indicator (JCI) for WJGE as 0.36.

RESPONSIBLE EDITORS FOR THIS ISSUE

Production Editor: *Lin-YuTong Wang*; Production Department Director: *Yun-Jie Ma*; Editorial Office Director: *Jia-Ping Yan*.

NAME OF JOURNAL

World Journal of Gastrointestinal Endoscopy

ISSN

ISSN 1948-5190 (online)

LAUNCH DATE

October 15, 2009

FREQUENCY

Monthly

EDITORS-IN-CHIEF

Anastasios Koulaouzidis, Bing Hu, Sang Chul Lee

EDITORIAL BOARD MEMBERS

<https://www.wjgnet.com/1948-5190/editorialboard.htm>

PUBLICATION DATE

August 16, 2021

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INSTRUCTIONS TO AUTHORS

<https://www.wjgnet.com/bpg/gerinfo/204>

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PUBLICATION ETHICS

<https://www.wjgnet.com/bpg/gerinfo/288>

PUBLICATION MISCONDUCT

<https://www.wjgnet.com/bpg/gerinfo/208>

ARTICLE PROCESSING CHARGE

<https://www.wjgnet.com/bpg/gerinfo/242>

STEPS FOR SUBMITTING MANUSCRIPTS

<https://www.wjgnet.com/bpg/gerinfo/239>

ONLINE SUBMISSION

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Prospective Study

Prospective evaluation of the hemorrhoid energy treatment for the management of bleeding internal hemorrhoids

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Author contributions: Kothari TH designed and conceptualized the study; Bittner K collected the data; Kothari TH, Bittner K, Kaul V and Kothari S contributed planning/conducting the study (literature review), interpretation of data, drafting/editing the manuscript, and approved the final draft.

Institutional review board

statement: The study was reviewed and approved by the Research Subjects Review Board (University of Rochester Medical Center; approval #780).

Informed consent statement: All study participants, or their legal guardian, provided informed written consent prior to study enrollment.

Conflict-of-interest statement: All authors have no conflict of interest to report.

Data sharing statement: No additional data are available.

Open-Access: This article is an open-access article that was

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Abstract

BACKGROUND

The hemorrhoid energy treatment (HET) system is a non-surgical bipolar electrotherapy device, which has previously demonstrated efficacy in the management of bleeding Grade I and II internal hemorrhoids; however, data is limited.

AIM

To prospectively assess the safety and efficacy of the HET device.

METHODS

This was an IRB-approved prospective study of 73 patients with Grade I or II internal hemorrhoids who underwent HET from March 2016 to June 2019. Patient factors and procedural data were obtained. A post-procedure questionnaire was administered by telephone to all patients at 1-wk and 3-mo following HET to assess for improvement and/or resolution of rectal bleeding and adherence to a stool softener regimen. A chart review was performed to observe recurrent symptoms and durability of response. Statistical analyses were performed using SPSS software (IBM; SPSS Version 25.0).

RESULTS

Seventy-three patients underwent HET during the study period. Mean post-HET follow-up was 1.89 years. Complete resolution of bleeding was reported in 65% at 1 wk ($n = 48$), with improvement in bleeding in 97.2% ($n = 71$) of patients. At 3-mo, resolution and/or improvement in bleeding was reported in 90% ($n = 64$) of patients. No procedure-related pain or adverse events were reported.

CONCLUSION

HET is well tolerated, safe and highly effective in the majority of our patients presenting with Grade I and II symptomatic internal hemorrhoids.

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Manuscript source: Invited manuscript

Specialty type: Gastroenterology and hepatology

Country/Territory of origin: United States

Peer-review report's scientific quality classification

Grade A (Excellent): 0
Grade B (Very good): B
Grade C (Good): 0
Grade D (Fair): 0
Grade E (Poor): 0

Received: December 16, 2020

Peer-review started: December 16, 2020

First decision: March 1, 2021

Revised: April 7, 2021

Accepted: July 19, 2021

Article in press: July 19, 2021

Published online: August 16, 2021

P-Reviewer: Lan C

S-Editor: Gao CC

L-Editor: A

P-Editor: Wang LYT



Key Words: Internal hemorrhoids; Bleeding hemorrhoids; Painless bleeding; Mucus; Constipation; Straining

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Core Tip: Bleeding internal hemorrhoids are a very common problem. More than 50% of population 50 years or older have issues with constipation leading to painless bleeding. Tremendous amount of money is spent in urgent care and emergency department visits for painless bleeding. Not many treatment modalities are available for internal hemorrhoids. Hemorrhoid energy treatment is a bipolar equipment for treatment of internal hemorrhoids grade I and II. Our study has reflected the benefits of this device through our prospective trial.

Citation: Kothari TH, Bittner K, Kothari S, Kaul V. Prospective evaluation of the hemorrhoid energy treatment for the management of bleeding internal hemorrhoids. *World J Gastrointest Endosc* 2021; 13(8): 329-335

URL: <https://www.wjgnet.com/1948-5190/full/v13/i8/329.htm>

DOI: <https://dx.doi.org/10.4253/wjge.v13.i8.329>

INTRODUCTION

Internal hemorrhoids (IH) are a very common cause of lower gastrointestinal bleeding (LGIB) with an estimated prevalence in the United States of 4.4%, accounting for an estimated 3.3 million ambulatory care visits annually[1]. Approximately 40% of patients with hemorrhoids are asymptomatic; however, those presenting with symptoms most often report painless bleeding[2]. Conventionally, Grade I and II bleeding IH have been managed with noninvasive therapies that combine dietary and lifestyle modifications, including increased oral fluid intake, reduction of fat consumption, avoidance of straining during bowel movements, and increased fiber intake[3].

For symptomatic patients, several non-surgical outpatient office-based treatments are currently available including rubber band ligation, infrared coagulation, sclerotherapy, bipolar diathermy, laser photocoagulation, and sclerotherapy[4]. The goal of non-surgical treatment is to decrease vascularity, reduce redundant tissue, and increase hemorrhoidal rectal wall fixation to minimize prolapse[3]. Though success has been demonstrated with the above-mentioned techniques, anorectal pain, recurrent bleeding, and recurrence of hemorrhoids are well-reported adverse events[5, 6].

A novel non-surgical bipolar electrotherapy device, the hemorrhoid energy treatment (HET) System, has previously demonstrated efficacy in the management of bleeding Grade I and II IH[7,8]. We present a prospective study to date evaluating the efficacy and safety of HET.

MATERIALS AND METHODS

This was an IRB-approved prospective cohort study (Research Subjects Review Board, University of Rochester, Study #780) conducted at our tertiary care referral center from 03/2016 to 06/2019. Adult patients (≥ 18 years old) with Grade I or Grade II IH scheduled for outpatient treatment with the HET system during the study period were eligible for inclusion. Written informed consent was obtained prior to study enrollment. All enrolled patients were contacted at 1-week post-procedure to assess improvement in rectal bleeding and self-reported compliance with stool softener use. At 3-mo post-procedure, the same survey was administered by telephone to evaluate if resolution or improvement in rectal bleeding had changed, and if compliance with stool softener use continued. All follow-up questionnaires were administered by telephone by one of the authors (Bittner K) utilizing a standardized script for each call. A concurrent chart review was performed to collect patient demographics, procedural and clinical data. All pre- and post-HET office visits with documented occurrences of

bleeding attributed to IH were recorded. Statistical analyses were performed with SPSS software (IBM, SPSS Version 25.0; Armonk, NY, United States).

HET Techniques

The HET Bipolar System (Medtronic, United States) is a modified anoscope, which incorporates bipolar forceps and includes a separate tissue temperature monitor console (Figure 1). HET was utilized with a commercially available electrosurgical generator (ERBE; Marietta, GA, United States)[9]. Ablation of IH can be achieved with the use of one of three techniques. All HET procedures were performed by two advanced endoscopists (TK, VK), with an average procedure time of less than 15 min.

Medtronic anoscopy technique: This technique includes insertion of the bipolar forceps under LED light provided at the top of the forceps and performing the procedure under direct vision. The superior hemorrhoidal plexus area, approximately 1 cm above the proximal extent of the IH, was grasped with the bipolar forceps. After confirming that the tissue grasped is sufficient (by means of same level approximation of three red lines on bipolar forceps handle), bipolar current was applied with using the recommended electrosurgical generator coagulation settings (effect 1, 5 watts; Figure 2A).

Standard technique: Our “standard technique” included the use of gastroscope inside the bipolar forceps to perform the IH ablation under endoscopic vision (Figure 2B). The concept is to target the superior hemorrhoidal plexus. This method was utilized for the majority of patients in our study ($n = 70/73$).

Modified technique: At our center, we developed a technique called the “modified HET technique” that utilizes use of pediatric biopsy forceps for tissue grasping in addition to the use of the standard endoscope to guide the bipolar forceps. This modified technique facilitates the capture of target rectal tissue when flat and difficult to grasp with the bipolar forceps alone. The pediatric biopsy forceps are used to gently pull the tissue immediately proximal to the IH, which allows the superior hemorrhoidal plexus area to enter the forceps better for optimal treatment (Figure 3).

RESULTS

A total of 73 patients were enrolled during the study period (March 2016 through June 2019). The majority of patients were female (53.4%), with mean age of 50.3 years (Table 1). Mean follow-up duration (post-HET) was 1.89 years. Thirty-six patients (49.3%) presented with Grade I and twenty-six (35.6%) with Grade II IH. Grade of IH was not available for 10/73 (13.7%) patients. In one patient, a Grade III hemorrhoid confirmed on colonoscopy immediately prior to treatment. Approximately half of patients (45.2%) failed conservative therapy prior to HET (defined as: stool softeners, fiber supplements and/or hydrocortisone suppositories). Most patients (90.4%) reported persistent painless rectal bleeding at the office visit immediately prior to referral for HET.

HET was performed with flexible sigmoidoscopy in all cases, using a standard gastroscope. Our “standard HET technique” was utilized in 70/73 patients. Three patients were treated with the “modified HET technique”. All patients were contacted by telephone at 1-wk and 3-mo post-procedure (Tables 2 and 3) to complete a questionnaire regarding resolution and/or improvement of bleeding symptoms, and compliance with stool softener use. All patients successfully completed the 1-wk questionnaire; however, 2 patients were unable to be contacted at 3-mo (response rate = 100% and 97.3%, respectively). At 1-wk post-procedure, complete resolution of bleeding was reported in 66% of patients ($n = 48/73$), with improvement in bleeding reported in 97.2% ($n = 71/73$) patients. Polyethylene glycol and/or other stool softeners were prescribed post-procedure to prevent constipation; however, at 3-mo post-HET, only 55% of patients reported continued use.

A concurrent chart review was performed to assess for recurrence or persistence of symptoms and durability of response. At 3-mo post-procedure, complete resolution of bleeding was reported in 62% of patients ($n = 44/71$), with improvement in bleeding reported in 90.1% ($n = 64/71$) patients. Six patients required a repeat HET (mean of 7.6 mo following initial treatment) for persistent rectal bleeding, with complete resolution reported after the 2nd treatment in 3/6 of these patients. Three patients continued to report persistent rectal bleeding despite repeat HET.

Table 1 Patient characteristics

Patient characteristics	n = 73
Age at HET (yr), mean	50.3
Female, n (%)	39 (53.4)
Race, n (%)	
Caucasian	58 (79.5)
African-American	14 (19.2)
Asian	1 (1.4)
Grade of hemorrhoids at time of HET, n (%)	
Grade I	36 (49.3)
Grade II	26 (35.6)
Grade III	1 (1.4)
Not reported	10 (13.7)

HET: Hemorrhoid energy treatment.

Table 2 Responses to telephonic questionnaire

Responses to telephonic questionnaire, 1 wk post-procedure (n = 73)					
Bleeding resolved		Bleeding improved		Use of stool softeners (post-HET)	
Yes, n (%)	No, n (%)	Yes, n (%)	No, n (%)	Yes, n (%)	No, n (%)
48 (65.8)	25 (34.2)	23 (92.0)	2 (8.0)	36 (49.3)	37 (50.7)

HET: Hemorrhoid energy treatment.

Table 3 Responses to telephonic questionnaire

Responses to telephonic questionnaire, 3 mo post-procedure (n = 71)					
Bleeding resolved ¹		Bleeding ¹ improved		Use of stool softeners (post-HET)	
Yes, n (%)	No, n (%)	Yes, n (%)	No, n (%)	Yes, n (%)	No, n (%)
44 (62.0)	27 (38.0)	20 (74.1)	7 (25.9)	39 (54.9)	32 (45.1)

¹A total of 64/71 (90.1%) patients reported complete resolution or improvement of bleeding post-hemorrhoid energy treatment.

HET: Hemorrhoid energy treatment.

There were no instances of pain or rectal discomfort during or immediately following the HET procedure. One patient reported self-limited post-procedure bleeding. No other adverse events were noted from the procedure.

DISCUSSION

IH are common and can be symptomatic with rectal bleeding in many patients. They are often difficult to treat and can lead to significant morbidity, affect quality of life of the patient and put a significant burden on healthcare. Several non-surgical treatment modalities are available for treatment of Grade I and II bleeding IH. Current treatment guidelines recommend outpatient office-based procedures such as rubber-band ligation (RBL), sclerotherapy or infrared coagulation for patients who remain symptomatic after lifestyle modifications have failed[10].

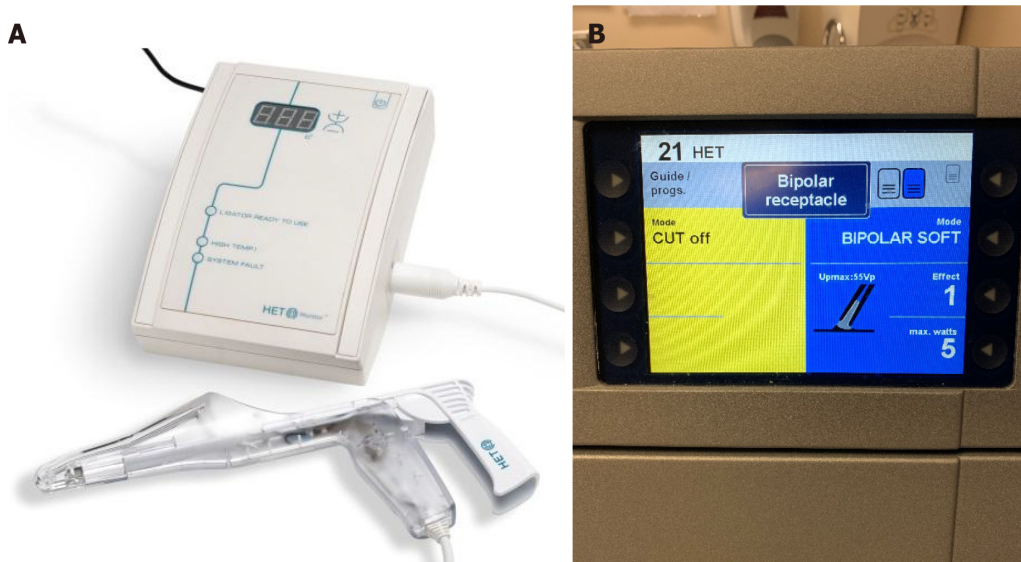


Figure 1 The hemorrhoid energy treatment bipolar system. A: Hemorrhoid energy treatment (HET) system with bipolar forceps and tissue temperature monitor. Permission for use of image granted by HET System, LLC; B: Electro-surgical generator with HET settings.

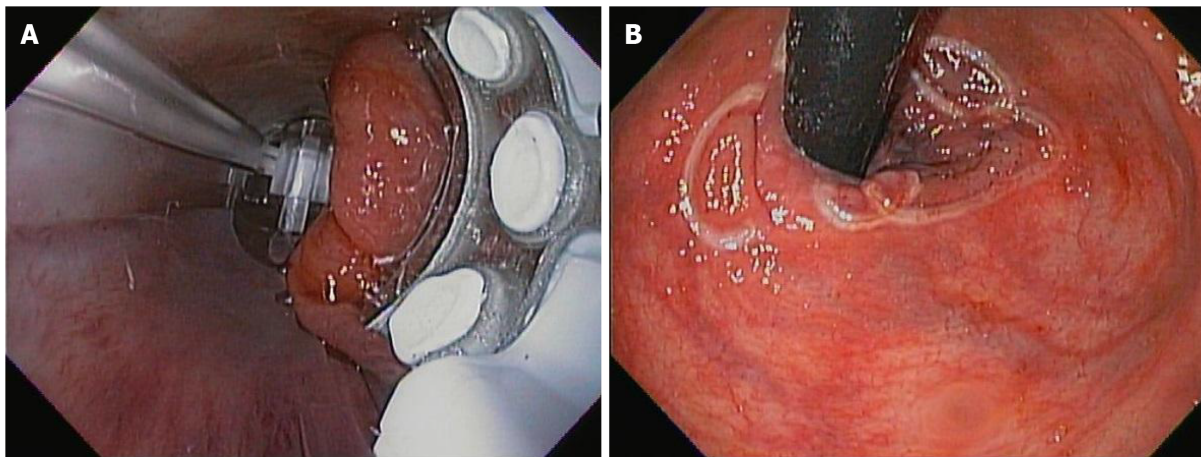


Figure 2 Antegrade view of internal hemorrhoids and retroflexed view of the anal verge. A: Antegrade view of internal hemorrhoids with a standard gastroscope; B: Retroflexed view of the anal verge post hemorrhoid energy treatment suggestive of treatment of multiple internal hemorrhoidal columns.

Rubber band ligation is the most frequently used procedure for hemorrhoid treatment. In a meta-analysis of 18 randomized controlled trials, RBL was noted to have a lower need for repeat treatments compared to sclerotherapy and infrared coagulation, although did cause significantly more pain reported in 25%-50% of patients[11-13].

Sclerotherapy is one of the oldest non-surgical therapy and involves injecting a sclerosant into the submucosa at the base of the hemorrhoid. Due to the nature of the procedure, there have been adverse events reported such as rectal fistulas and life-threatening retroperitoneal sepsis[14]. In a meta-analysis of randomized controlled studies comparing RBL, sclerotherapy and surgery, sclerotherapy was less effective than rubber band ligation and surgery. Infrared coagulation is less effective than banding or sclerotherapy and requires repeat treatment sessions[11].

HET is a novel non-surgical treatment for IH and has been reported to be both safe and effective in prior studies[7-9]. These studies have had limitations due to the retrospective nature of the study and small sample size. Piskun and Tucker[9] performed a direct comparison of the HET system with infrared coagulation in a live porcine model with favorable outcomes. The HET device combined target tissue compression with precise application of much lower temperature (55 °C) *vs* that of the infrared coagulation probe (149 ± 11.1 °C), minimizing heat-related collateral damage to tissues adjacent to the treatment areas. The authors concluded that the treatment with the HET System would cause less procedural pain and less post-procedural

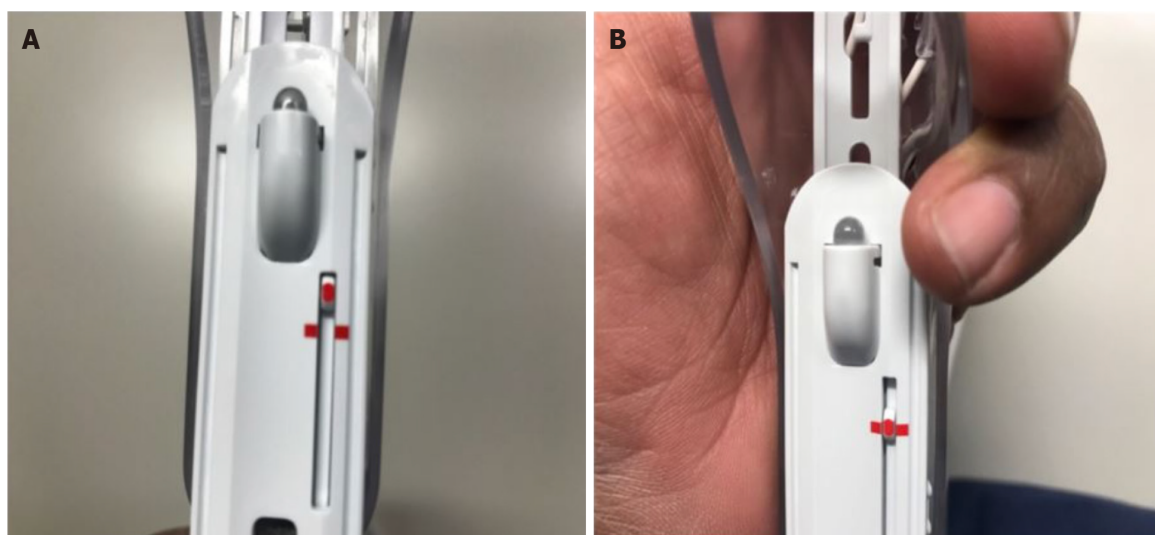


Figure 3 The pediatric biopsy forceps. A and B: Sufficient entrapment of the mucosa above the internal hemorrhoids is indicated with alignment of all three red lines.

adverse events *vs* existing non-surgical modalities for treatment of IH[9]. In 2013, Kantsevov and Bitner[8] conducted a retrospective study of examining the use of HET for the indication of actively bleeding IH. All patients in this cohort ($n = 23$) tolerated the treatment without any pain or discomfort. No adverse events were reported in the study[8]. In 2016, Crawshaw *et al*[7] reported the safety and efficacy of HET technology in a prospective case series of 20 patients with bleeding improvement seen in $> 80\%$ of the patients.

Our study demonstrates the safety and efficacy of the HET platform in the treatment of Grade I and Grade II IH. Nearly half of patients had failed guideline-based conservative therapy prior to referral for HET. The majority of our cohort reported no immediate post-procedural pain or bleeding. Complete resolution and/or improvement in bleeding symptoms were reported in 97.2% and 90.1 % of patients at 1-week and 3-months post-procedure, respectively.

The main limitations of this study were relatively small sample size ($n = 73$), lack of comparison or control arm, and is our single-center's experience with HET use. The potential for lack of generalizability may exist due to the level of expertise of the endoscopists performing the HET procedure at our institution.

CONCLUSION

Our study represents one of the largest prospective studies reporting safety and efficacy for the use of HET system in patients with symptomatic Grade I and II IH. Further multi-center prospective studies are needed to validate the efficacy and safety of the device. In addition, these studies should also assess if the use of stool softeners for a brief period post-HET prevents recurrence of rectal bleeding.

ARTICLE HIGHLIGHTS

Research background

Painless rectal bleeding (*i.e.*, Grade I and Grade II Internal hemorrhoids) can be effectively treated with hemorrhoid energy treatment (HET). Our study has demonstrated that the procedure is safe, well tolerated and clinically effective for most patients.

Research motivation

There has been limited treatment for internal hemorrhoids, hence this manuscript is intended to add real-world clinical data to the literature.

Research objectives

To educate readers with clinical data regarding treatment of bleeding internal hemorrhoids with the help of HET system.

Research methods

This research study was a prospective cohort design.

Research results

The majority of patients reported complete resolution and/or improvement in bleeding resulting from internal hemorrhoids at 3-mo post-procedure.

Research conclusions

HET system can make a significant impact in treatment of bleeding internal hemorrhoids.

Research perspectives

Further research should be performed to expand upon our findings.

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